ESHOO-INSLEE-BARTON BIOSIMILARS AMENDMENT
SECTION-BY-SECTION SUMMARY

Licensure of Biological Products as Biosimilar

Sets forth the data requirements for FDA licensure of a biological product as biosimilar to a reference product. Provides a period of data exclusivity for reference products and market exclusivity for the initial interchangeable biosimilar. Establishes a process for the FDA to issue product class-specific guidance, including the criteria by which biosimilarity, interchangeability, and immunogenicity will be determined.

Required Information – Requires biosimilar applicants to submit information demonstrating that:

- Their biological product is biosimilar to a licensed reference biological product based upon data derived from analytical studies demonstrating that the biosimilar is highly similar to the reference product notwithstanding minor differences in clinically inactive components and animal and clinical studies including the assessment of immunogenicity and pharmacokinetics/pharmacodynamics sufficient to demonstrate safety, purity and potency in one or more conditions for which the reference product is licensed.

- The biosimilar and reference product utilize the same mechanisms of action to the extent these mechanisms are known.

- The conditions of use in the biosimilar's labeling are previously approved for the reference product.

- The route of administration, dosage form, and strength of the biosimilar are the same as the reference product.

- The manufacturing, processing, packing, and storage facilities of the biosimilar meets standards to assure safety, purity, and potency.

Waiver – The FDA may determine that any of the above requirements is unnecessary in a biosimilars application.

Evaluation by Secretary – The FDA shall license a biological product as a biosimilar if it determines the product is biosimilar to or interchangeable with the reference product and the applicant consents to an inspection of its production facility.

Interchangeability – The FDA may make a determination that a biosimilar is interchangeable with a reference product. The biosimilar product must be biosimilar to the reference product and must produce the same clinical result as the reference product. There must be no increased safety risk or diminished efficacy as a result of alternating use between the reference product and the biosimilar.

One Reference Product per Application – A biosimilar may only be evaluated against one reference product.

Review of Applications – Biosimilar applications must be reviewed by the same FDA reviewing division that licensed the reference product.

Risk Evaluation and Mitigation – Licensed biosimilars are subject to the same risk evaluation and mitigation strategy requirements as other biological products.

Select Agents, Toxins and Controlled Substances – Before licensing a biosimilar that is listed as or contains substances listed as select agents, toxins or controlled the FDA must determine there is no increased risk to the security or health of the public.

Exclusivity for First Interchangeable Biosimilar – The first product licensed as an interchangeable biosimilar is granted market exclusivity for one year after the date of the first commercial marketing of the biosimilar or 18 months after the end of any patent infringement litigation related to the biosimilar, whichever is earlier. In any case, such exclusivity may not extend beyond 42 months of patent litigation or, if applicant has not been sued, 18 months after FDA approval.

Data Exclusivity for Reference Product – Provides for 12 years of data exclusivity for reference products. Like drugs regulated under Section 505, there will be provided an additional six months of exclusivity for pediatric clinical testing when such tests are requested by the FDA.

Filing Period – An application for a biosimilar may not be submitted until four years after the licensing of the reference product.

First Licensure – The 12-year data exclusivity period and four-year application delay does not apply to supplements to licensed biologics or to subsequent applications made by a biologic manufacturer related to changes which result in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength. Also applications related to modification to the structure of the biologic that do not result in a change in safety, purity, or potency.

Guidance Documents – The FDA may issue guidance documents for licensure of biosimilars and must provide opportunity for public comment on any proposed guidance. The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

Requirement for Application Consideration – The issuance (or non-issuance) of guidance does not preclude review or action on a biosimilars application.

Requirement for Product Class-Specific Guidance – Product class-specific guidance must include the criteria by which biosimilarity and interchangeability will be determined. The FDA may determine that current state of science and experience does not allow approval of a particular product or product class. The FDA may issue subsequent guidance modifying or reversing previously issued guidance documents.

Naming – The FDA must ensure that the labeling and packaging of a biosimilar bears a name that uniquely identifies it and distinguishes it from the reference product or other biosimilars.

Patent Notices; Relationship to Final Approval

Requires the FDA to publish notice identifying the reference product identified in the application and notify the reference product sponsor within 30 days of acceptance, thereby initiating a timely process that enables follow-on applicants and patent holders to identify relevant patents.

Confidential Information – Requires entities receiving information in this process to designate one or more individuals whom must execute an agreement pursuant to FDA regulations requiring them to maintain the confidentiality of such information and use it solely for the purposes set forth in the legislation.

Public Notice by the Secretary – Requires the FDA to publish a notice in the Federal Register within 30 days of acceptance of a biosimilar product application identifying the reference product identified in the application and the name and address of an agent designated by the biosimilar applicant.

Exchanges Concerning Patents with Reference Product Sponsor – Within 30 days of acceptance of application by the FDA, the biosimilar applicant must provide the product sponsor a copy of the application and information concerning the biosimilar product and its production. Within 60 days of the receipt of this information, the reference product sponsor must provide the biosimilar applicant a list of its relevant patents. The reference product sponsor must provide a list of any patents granted or acquired after this time within 30 days of issuance or acquisition.

Exchanges with Interested Third Parties – At any time following FDA notice of the biosimilar application, a party other than the reference product sponsor that owns relevant patents may provide notice to the applicant. Within 30 days of the receipt of this notice the biosimilar applicant must provide the interested third party a copy of the application and information concerning the biosimilar product and its production. Within 90 days of receipt of this information the interested third party must provide the biosimilar applicant a list of its relevant patents. The interested third party must provide a list of any patents granted or acquired after this time within 30 days of issuance or acquisition.

Identification of the Basis for Infringement – For any relevant patent identified by the reference product sponsor or an interested third party, the patent holder must explain in writing why the patent will be infringed, whether the patent is available for licensing, and the number and date of expiration of the patent.

Certification by Applicant Concerning Identified Relevant Patents – Within 45 days of the identification of relevant patents by the reference product sponsor or an interested third party, the biosimilar applicant must send a written statement regarding each patent to the patent holder stating that the applicant will not begin marketing the biosimilar prior to the date of expiration of the patent or providing a detailed written explanation as to why the biosimilar would not infringe the patent or why the patent is not enforceable.

Action for Infringement Involving Reference Product Sponsor – If a product sponsor or interested third party sues for infringement within 60 days of receipt of the certification by the biosimilar applicant, and the court in which the action is brought determines the patent is infringed, enforceable and valid prior to the expiration of the applicable data exclusivity period,

the FDA shall make approval of the biosimilar application effective after the expiration of the infringed patent.

Products Previously Approved Under Section 505 of the Federal Food, Drug, and Cosmetic Act – Provides a transition for biologics approved under Section 505 of the FDCA to establish a unified statutory scheme for all complex proteins. Biosimilar applications could be filed under Section 505 or Section 351 of the PHSA for 10 years after the date of enactment. Thereafter, all biologics and biosimilars would be regulated under Section 351.

Fees Relating to Biosimilar Biological Products – Ensures sufficient FDA resources by establishing a user fee program for biosimilar biological product applicants to offset costs for review of biosimilar product applications.